REMARKS

Please enter this Amendment and then reconsider the rejections before passing this case to an allowance.

Claim Amendments

Claim 1 as amended defines the screen material layer as being comprised of two layers. This is supported in the original specification throughout. Attention is invited, for instance, to pages 7, 12-13, and 23-24.

Amended claim 1 recites "adapted for receiving a pharmaceutical patch." This language is drawn from the specification as a whole and from the principle established in Ex Parte Conner, 215 USPQ (BNA) 384 (BOPI 1981) (explaining "adapted for application to the human skin" imposes a claim limitation that cannot be ignored in considering patentability), copy attached.

Amended claim 2 is better aligned linguistically with the amended claim 1.

Amended claim 3 now depends from claim 2.

As amended, claim 5 is now presented as an independent claim.

New claim 13 is based on the original claims and the original specification throughout.

New claim 14 finds basis in the original specification throught and the original claims.

New claim 15 finds basis in the original specification throught and the original claims.

New claims 16 and 17 find support in the specification throughout, although pages 18-20 are noted for the Examiner's convenience.

Please reconsider and withdraw the formality rejection of claim 3.

Amended claim 3 is intended to address and overcome the rejection under 35 U.S.C. §112(¶2). The Examiner's constructive comment is acknowledged.

Interview Summary

Applicants representative acknowledges the courtesies and constructive comments from the Examiners during the personal interview conducted on July 16, 2004.

The claim language "patch package" was discussed. Applicants consider the term definite.[1] The term is consistently used throughout the specification in connection with a patch that can contain a drug product. See, e.g., pages 2-3. The Examiners appear to consider "patch" as a statement of intended use, and appear to have construed the claim language as pertaining to only a package, which, if this is case, would read 'patch' out of the claims. The Examiners suggested Applicants consider other wording.

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[1] The claims are considered definite as a person skilled in the art, upon consulting the specification, would be able to determine the scope of the claims. See, in general, W.L. Gore & Associates v. Gorlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469U.S. 851 (1984).

Applicants submitted the references did not disclose or suggest the features in proposed amended claim 1 and proposed claims 13 and 14, nor did such references suggest the result-effective variables in these claims. It was suggested that the recitations in the claims were not the necessary, inevitable, result of practicing any one of the applied items of prior art.

It appears, however, the Examiners consider the numerical recitations in the claims were inherent or were optimized variations of the references.

It was agreed that claims to a combination of the "patch package" and a "patch" therein would be more favorably considered subject to a further search.

The Examiners said they had a requested a the PTO translation of JP-07-28550-U but it was unfortunately not then completed. The Examiners said they would forward a copy to Applicants' representative as soon as it became available. Applicants representative acknowledges the Examiners' courtesy and thoroughness. Applicants' representative confirms the Examiners provided the translation via facsimile on July 21, 2004, and thanks the Examiners for providing the information.

Please reconsider and withdraw the rejection of claims 1 and 4.

Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1 and 4 under 35 U.S.C. §103(a) over JP 04-189779A (Yuichi) in view of U.S. Patent No. 4,861,632 (Caggiano).

The two documents would not have been combined by a person of ordinary skill in the art at the time Applicants made their inventions. Even if, *arguendo,* the two

documents were combined, their combined 'teachings' would not have suggested the present claimed inventions to the aforesaid person of ordinary skill in the art.

As brought out in claims 1-4 and in new claim 13, an embodiment of the present invention concerns a patch package comprised of two sheets, provided each sheet consists of four layers.

The primary Yuichi document lacks or does not expressly disclose the use of two sheets to form a bag. The Yuichi document apparently discloses a bag made from one sheet and the sheet has three layers. The Yuichi document does not apparently disclose or suggest two sheets. The Yuichi document does not apparently disclose or suggest that the two sheets have at least four layers.

The primary Yuichi document lacks or does not expressly disclose the use of two sheets to form a bag and a moisture permeability rate of 40-120 $g/m^2/day$.[2]

The primary Yuichi document also lacks or does not apparently describe a bag in which a layer contains 20-40 wt% of organic filler.

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[2] When an alleged prior art patent, including drawings, is silent on a quantitative relationship, rejections assuming the existence of any such quantitative relationship are undermined, and subject to being reversed. Hockerson-Halberstadt Inc. v. Avia Group International Inc., 58 USPQ2d (BNA) 1487, 1491 (Fed. Cir. 2000); Ex parte Brown, 19 USPQ2d (BNA) 1609, 1612 (BOPI 1990) ("since the prior art is silent as to this feature, we are unable to sustain the rejection ..."); Ex parte Isaksen 23 USPQ2d (BNA) 1001, 1006 (BOPI 2001), ("Forbes patent[s] are completely silent as to any sharpening effect and do not describe with any specificity what results ... magnetic treatment had on the razor blade edge," rejection reversed).

The claims are considered patentable over the prior art Yuichi reference. Applicants respectfully submit the record does not contain clear and convincing evidence that the functional or characteristic recitations in the claims necessarily flow and/or are inevitably present in the teachings of the prior art considered by the Examiner. There are other attributes undisclosed in the prior art considered by the Examiner that could and/or necessarily effect the functional or other characteristics of such prior art structures. Applicants accordingly respectfully submit the application of prior art is not warranted. See, e.g., Ex Parte Levy, 17 USPQ 2d 1461, 1464 (Bd. Pat. App. & Inter. 1990), copy attached.

The secondary Caggiano document (U.S. Patent No. 4,861,632) lacks or apparently does not expressly disclose the use of two sheets in which the two sheets each have at least four layers. The Caggiano document apparently discloses sheets that have three layers as depicted by reference numbers 3, 4 and 5 in Figure 1. The Caggiano document refers to paper toweling as the absorbing material (column 2, line 50 and 52-53; column 4, lines 39-41), and even if it was combined with a dessicant (column 4, lines 45-49), the paper with a potential enhanced moisture absorbancy would not have suggested the hygroscopic layer as recited in claim 1. The Caggiano document would not have suggested that two of the four layers form a screen material layer.

The two documents do not appear suited for combination.

Even if, *arguendo*, the two documents were combined, their combined 'teachings' would not have suggested, for instance, a patch package comprised of a first sheet and a second sheet in which each sheet has at least four layers. Therefore, even if, *arguendo,* a person of ordinary skill in the art would have made the substitution and replacement

hypothesized in the Office Action, the resultant combined disclosure would not have suggested the present claimed inventions. The combination apparently would lack and would not have suggested two sheets in which each sheet has at least four layers.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection.

Please reconsider and withdraw the rejection of claims 2 and 3.

Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 2 and 3 over "Yuichi-Caggiano as applied to claim 1 above, and futher in view of Wilking (US 5,698,217)."

Applicants respectfully submit that factual basis is not seen for the modifications proposed in the Office Action for the rejection.

Inasmuch as the combination of Yuichi-Caggiano apparently lacks and does not disclose a patch package comprised of a first sheet having four layers and a second sheet having four layers, it follows that neither would have suggested two of the four layers can form a screen material layer as in claim 1 from which claims 2 and 3 depend. The Yuichi and Caggiano documents do not apparently disclose the first and second resins of LDPE, nor the screen layer being an HDPE-foil laminate. The cited passages in the Wilking document do not teach the four layer structure, do not teach the first and second resins of LDPE in a four layer structure, but do teach using paper. In the Wilking document, the cited passages refer to a laminate containing paper/foil/polyethylene, paper/foil/vinyl primer, or paper/foil/polyvinyldichloride (column 4, lines 47-49) or laminates involving "paper or foil ..." (column 4, line 51) (emphasis added). Basis is not

seen whereby the apparent preference for "paper"would have suggested the structure according to claim 1, nor is it seen where the Wilking document would have motivated the hypothesized modification of either the Yuichi or Caggiano documents towards the present inventions. Indeed, the Wilking reference requires a dessicant package 20 at column 4, lines 55-60 and column 5, lines 21-22, which would not have suggested the present invention, nor the features missing from in the Yuichi reference.

Please reconsider and withdraw the rejection of claim 5.

Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claim 5 over "Tsukahara et al (H-7-28550 supplied by applicant) in view of Yuichi-Caggiano-Wilking as applied to claims 1-4 above."

Applicants respectfully point out that in the Tsukahara document the package is different from and would not have suggested the claimed inventions. For instance, in the Tsukahara document sheets are bonded to each other by an adhesive. In contrast, in the present claimed invention, the sheets are heat sealed about portion(s) of their periphery. Applicants also respectfully point out that the Patent Office has said the Tsukahara document does not expressly disclose a bag with moisture absorbing capabilities.

Accordingly, Applicants respectfully submit that their inventions would not have been suggested to a person of only ordinary skill in the art by Tsukahara alone or in combination with Yuichi-Caggiano-Wilking as applied to claims 1-4.

Conclusion:

Applicants have endeavored to respond in full to the pending Office Action, but if the Amendment is found wanting in any respect, please telephone the undersigned. Applicants earnestly, but respectfully, submit that their application is in condition for an Allowance and respectfully solicit such Notice.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

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Ex Parte Conner, 215 USPQ 384 (BdPatApp&Int 1981)

Ex Parte Conner

(BdPatApp&Int)
215 USPQ 384

Opinion dated Dec. 18, 1981
U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences

Headnotes

PATENTS

1. Patentability--Composition of matter (§ 51.301)

Although, normally, claims directed to compositions are not rendered patentable merely by recitation in claims of statement of intended use, Examiner must present evidence that claimed composition, apart from statement of intended use, was unpatentable.

2. Patentability--Composition of matter (§ 51.30)

Characterization in claims that compositions are "adapted for application to human skin" imposes limitation in the claims that cannot be ignored in considering patentability.

Particular patents--Sun Screens

Conner, Benzalphthalides as Broad Spectrum Sun Screens, rejection of claims 1-8, reversed.

Case History and Disposition:

Page 384

Appeal from Art Unit 125.

Application for patent of Donald E. Conner, Serial No. 042,013, filed May 24, 1979, continuation-in-part of application, Serial No. 014,598, filed Feb. 23, 1979, abandoned. From decision rejecting claims 1-8, applicant appeals (Appeal No. 465-87). Reversed.

Attorneys:
L. Chasan, Union, N.J., for appellant.

Judge:
Before Serota and Merker, Examiners-in-Chief, and Lovell, Acting Examiner-in-Chief.

Opinion Text

Opinion By:
Serota, Examiner-in-Chief.

This is an appeal from the Examiner's decision finally rejecting claims 1 to 8. Claims 9 to 18, the other claims in this application, have been indicated to be allowable.

Claim 1 is illustrative and reads as follows:

> 1. A composition adapted for application to the human skin comprising a cosmetic oil carrier containing distributed therein from an effective amount to provide substantial protection against erythemal and tanning radiation up to the limit of solubility therein of a benzalphtalide.

The references relied upon are:

Table set at this point is not available. See table in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

All of the claims on appeal stand rejected under 35 USC 103 as obvious from various combinations of the above identified references.

[1] We will not sustain any of the Examiner's rejections. Although normally claims directed to compositions are not rendered patentable merely by a recitation in the claims of a statement of intended use (see In re Pearson, 494 F.2d 1399), 181 USPQ 641 (CCPA 1974), the Examiner must present evidence that the claimed composition, apart from the statement of intended use, was unpatentable. Here, we have no such evidence.

[2] The claims require that the claimed compositions be "adapted for application to the human skin" and are composed of "a cosmetic oil carrier* * *" in addition to a benzalphthalide. The references relied upon by the Examiner do not disclose benzalphthalide in combination with a cosmetic oil carrier which compositions are suitable for application to the human skin. The various compositions of several of the references contain additional ingredients, e.g. sodium hydroxide or styrene, which would have rendered the compositions unsuitable for application to the human skin. The characterization in the claims that the compositions are "adapted for application to the human skin" imposes a limitation in the claims which cannot be ignored in considering the patentability of the claims. There is no disclosure in the references which would have motivated the worker in the art to modify the compositions disclosed in the references to include a cosmetic oil carrier and/or to render the compositions of the references suitable for application to the skin.

Accordingly, the decision of the Examiner is reversed.

- End of Case -

ISSN 1526-8535

FULL TEXT OF CASES (USPQ2D)
All Other Cases
Ex parte Levy (BdPatApp&Int) 17 USPQ2d 1461 (10/16/1990)

Ex parte Levy (BdPatApp&Int) 17 USPQ2d 1461

Ex parte Levy

U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences
17 USPQ2d 1461

Decided October 16, 1990
No. 90-1864

Headnotes

PATENTS

1. Patentability/Validity - Anticipation - Identity of elements (§ 115.0704)

Factual determination of anticipation requires disclosure in single reference of every element of claimed invention, and examiner must identify wherein each and every facet of claimed invention is disclosed in applied reference.

2. Patentability/Validity - In general (§ 115.01)

Patentability/Validity - Anticipation - Prior art (§ 115.0703)

Initial burden of establishing prima facie basis to deny patentability rests upon examiner; examiner, if relying upon theory of inherency, must provide basis in fact and/or technical reasoning to reasonably support determination that allegedly inherent characteristic necessarily flows from teachings of applied prior art.

3. Patentability/Validity - Anticipation - Prior art (§ 115.0703)

Examiner erred by rejecting claims for biaxially oriented catheter balloon as anticipated by prior art which does not disclose such biaxially oriented balloon and which has not been shown to be inherently biaxially oriented.

4. Patentability/Validity - Obviousness - Relevant prior art - Particular inventions _ (§ 115.0903.03)

Examiner erred by rejecting claims for biaxially oriented balloon catheter under 35 USC 103 based upon combined disclosure of two prior art references, one of which was relied upon solely for disclosed use of high viscosity polyethylene terephthalate tubing and the other which was presupposed by examiner to disclose biaxially oriented catheter balloon, since examiner has not established that resulting catheter balloon using high viscosity tubing is biaxially oriented.

Case History and Disposition:

Page 1461

Application of Stanley B. Levy, serial no. 287,234, filed Dec. 21, 1988, which is a division of serial no. 914,108, filed Oct. 1, 1986, now Re. 32,983, granted July 4, 1989; and a reissue of serial no. 510,812, filed July 5, 1983, now patent no. 4,490,421, granted Dec. 25, 1984, for balloon and manufacture thereof. From examiner's rejection of claims 13 through 17 and 25 (James Seidleck, primary

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examiner), applicant appeals. Reversed.

Attorneys:
Louis H. Rombach, Wilmington, Del., for appellant.

Judge:
Before Steiner, Tarring, and J. Smith, examiners-in-chief.

Opinion Text

Opinion By:
Steiner, examiner-in-chief.

This is an appeal from the final rejection of claims 13 through 17 and 25, which are all of the claims remaining in this application for reissue of U.S. Patent No. 4,490,421.
The subject matter on appeal is directed to a polymeric balloon exhibiting properties which enable its use as a catheter balloon for medical dilation procedures, such as coronary angioplasty wherein a catheter with a balloon at a distal end thereof is inserted into coronary arteries and inflated. The balloon must be capable of exerting sufficient pressure to dilate stenotic lesions without rupture of the balloon. Claims 13 and 25, the only independent claims on appeal, read as follows:

13. *High molecular weight, biaxially oriented, flexible polymeric balloon having a wall tensile strength of at least 31,714 psi (218.86 MPa).*
25. *High molecular weight, biaxially oriented, flexible polyethylene terephthalate dilatation catheter balloon.*
The references relied upon by the examiner are:

Wyeth et al. (Wyeth)	3,733,309	May 15, 1973
Schjeldahl et al. (Schjeldahl '989)	4,413,989	Nov. 8, 1983 1
Schjeldahl et al. (Schjeldahl '000)	4,456,000	June 26, 1984 2

Claims 13, 14, 16, 17 and 25 stand rejected under 35 U.S.C. 102 as anticipated by Schjeldahl. Claims 13 through 17 stand rejected under 35 U.S.C. 103 based upon "Schjeldahl et al in view of Wyeth as set forth in the Final Rejection" (paragraph bridging pages 3 and 4 of the Answer). We reverse each rejection.

The Rejection of Claims 13, 14, 16, 17 and 25 Under 35 U.S.C. §102.

[1] The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention. *In re Spada,* — F.2d —, 15 USPQ2d 1655 (Fed. Cir. 1990); *In re Bond,* — F.2d —, 15 USPQ2d 1566 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.,* 850 F.2d 675, 7 USPQ2d 1315 (Fed. Cir. 1988); *Constant v. Advanced Micro-Devices, Inc.,* 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988); *Alco Standard Corp. v. TVA,* 808 F.2d 1490, 1 USPQ2d 1337 (Fed. Cir. 1986); *In re Marshall,* 578 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Arkley,* 455 F.2d 586, 172 USPQ 524 (CCPA 1972). Moreover, it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference. *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick,* 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).
Each of the independent claims on appeal defines a polymeric balloon which is "biaxially oriented." Ergo, in order to establish a *prima facie* basis to defeat the patentability of independent claims 13 and 25 under 35 U.S.C. §102, the examiner is obliged to point out where Schjeldahl discloses a *biaxially oriented* polymeric balloon. The tenor of the final rejection and Answer presupposes that Schjeldahl discloses a biaxially oriented polymeric balloon. See, for example, page 5 of the Final Rejection wherein the examiner states
he reference clearly teaches a biaxially oriented balloon catheter, and states that it is made by injection blow molding.
See, also, page 5 of the Answer wherein the examiner states
rguments that the references don't disclose a biaxially oriented PET (polyethylene terephthalate) balloon catheter is contrary to what is *clearly stated* in the references (emphasis supplied).
The examiner does not point to, and we do not find, any express disclosure in Schjeldahl of a biaxially oriented polymeric balloon.
It would appear that the relevant evulgations in Schjeldahl which may have led the examiner to his determination are:
(a) an expander 3 formed *from* a thin, flexible inelastic, high tensile strength, *biaxially oriented* synthetic plastic material

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(column 2 of Schjeldahl '989, lines 63 through 65, emphasis supplied);
(b) The expander 30 is preferably formed *from* a suitable synthetic plastic material, such as *biaxially oriented* polypropylene, *by an injection blow molding operation* and, as such, is substantially inelastic in both the axial and radial directions and may, for example, have a finished wall thickness in the range of

from 0.005 to 0.200 millimeters, 0.025 millimeters being typical (column 6 of Schjeldahl '989, lines 45 through 52, emphasis supplied);
(c) It has been found that an expander of the above-dimensional characteristics can withstand internal inflation pressure in excess of 7 atmospheres without fear of rupture (column 6 of Schjeldahl '989, lines 62 through 65);
(d) injection blow molding step used to form the expander 30 (column 8, lines 16 and 17);
(e) the expander 30 is formed *from* a *biaxially oriented* thin plastic material capable of withstanding relatively high internal pressures without rupture and without exceeding the elastic limit for the material itself (column 10 of Schjeldahl '989, lines 32 through 36, emphasis supplied);
(f) the expander 82 is preferably formed *from* a suitable synthetic plastic material such as *biaxially oriented polypropylene* or *biaxially oriented polyethylene terephthalate by an injection molding operation* and, as such, is substantially inelastic in both the axial and radial direction (column 12 of Schjeldahl '989, lines 22 through 37, emphasis supplied); and
(g) Apparatus as in claim 1 wherein said non-elastic expander member comprises a longitudinally extending thin, flexible, tubular element *formed from a biaxially oriented* synthetic plastic material surrounding said outer tubular member with opposed ends thereof secured to said outer tubular member at spaced apart locations proximate said distal end thereof (claim 8 of Schjeldahl '989, emphasis supplied).
These excerpts do not justify the determination that Schjeldahl discloses a biaxially oriented polymeric balloon.
According to Schjeldahl, the *starting* material is a biaxially oriented synthetic plastic material, such as polyethylene terephthalate. The *final article, i.e.,* the expander or catheter balloon, is *not characterized as biaxially oriented.* Moreover, it would appear to be *undisputed* that the *only* method disclosed by Schjeldahl for transforming the biaxially oriented *starting* plastic into the *final* catheter balloon, *i.e.,* injection blow molding, is *not* capable of producing a biaxially oriented catheter balloon. In fact, it is *undisputed* that injection blow molding would *destroy* the biaxial orientation of the plastic starting material. We refer to the Belcher affidavits, Exhibits V, VI and VIII, 4 which factually set forth the differences between "injection blow molding" and "injection stretch blow molding," and support the conclusion that the "injection blow molding" process disclosed by Schjeldahl could not possibly produce a biaxially oriented polymeric balloon. 5
Indeed, the examiner agrees with appellant's position that injection blow molding could *not* produce a biaxially oriented balloon. See, for example, page 5 of the Final Rejection wherein the examiner states:
tatements that injection blow molding without stretching will not produce a biaxially oriented article are *true* ... (emphasis supplied).
The examiner goes on, in the same sentence, to state:
but since the reference produces a biaxially oriented article, clearly a stretching step must be used.
Again, on page 5 of the Answer, the examiner states:
Since Schjeldahl et al produces a biaxially oriented article it follows that a stretching step must be used in the injection blow molding process.
The inescapable facts are that Schjeldahl does not disclose a biaxially oriented catheter balloon and does not mention a stretching step.
[2] The examiner also relies upon the theory that Schjeldahl's catheter balloon is inherently biaxially oriented. On page 4 of the Answer, the examiner points out that inasmuch as the Patent and Trademark Office does not have the requisite laboratory equipment for testing, the burden shifts to appellant. However, the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests

upon the examiner. *In re Piasecki,* 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably

support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. *In re King,* 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); *W.L. Gore & Associates, Inc. v. Garlock, Inc.,* 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); *In re Oelrich,* 666 F.2d 578, 212 USPQ 323 (CCPA 1981); *In re Wilding,* 535 F.2d 631, 190 USPQ 59 (CCPA 1976); *Hansgirg v. Kemmer,* 102 F.2d 212, 40 USPQ 665 (CCPA 1939). In our opinion, the examiner has not discharged that initial burden.

Schjeldahl does not provide any working example revealing the process conditions employed to produce the catheter balloon. We have *only* a general invitation to employ "injection blow molding." As previously discussed, it is undisputed that injection blow molding would *not* have produced a biaxially oriented balloon and would have destroyed the biaxially orientation of a polymeric starting material. Schjeldahl does not disclose any particular tensile strength of the catheter balloon. We do not find sufficient factual basis or cogent scientific reasoning to support the conclusion that Schjeldahl's disclosure with respect to the ability of the catheter balloon to "withstand an internal inflation pressure in excess of 7 atmospheres without fear of rupture" (column 6 of Schjeldahl '989, lines 63 through 65) *necessarily* means that the catheter balloon is biaxially oriented. According to the membrane equation calculations reported in Levy's declaration (Exhibit IV), Schjeldahl's balloon could not possibly exhibit the tensile characteristics of a biaxially oriented balloon. Levy's calculations are *inconsistent* with those of Pinchuk (Exhibit III). Suffice it to say, the conflicting calculations taint the factual determination of inherency with impermissible conjecture. Indeed, the examiner, in the paragraph bridging pages 4 and 5 of the Answer, states that

the membrane equation used to determine the tensil [sic, tensile] strength can be manipulated to produce any desired value, and thus is misleading.

Nevertheless, the examiner goes on to favor Pinchuk's calculations by stating in that same paragraph that

ertainly use of the typically used wall thickness disclosed in Schjeldahl et al with the average radius, as done in the Pinchuk Declaration would be reasonable.

As noted above, the conflicting results obtained by applying the membrance equation, and the examiner's acknowledgment that that equation "can be manipulated to produce any desired value," underscore the speculative nature upon which the determination of inherency rests.

We do not find sufficient cogent technical reasoning and/or objective evidence to support the conclusion that Schjeldahl's characterization of the catheter balloon as inelastic in the axial and radial direction *necessarily* means that the catheter balloon is biaxially oriented. The characteristic "inelastic," as employed by Schjeldahl, apparently means that the catheter balloon will expand to a preformed diameter to enable precise measurement of the pressures exerted on the inner wall of the artery during the dilation procedure (column 4 of Schjeldahl '989, lines 12 through 17).

[3] In summary, Schjeldahl does not disclose a biaxially oriented catheter balloon. We do not find a sufficient basis to support the determination that Schjeldahl's balloon is *inherently* (necessarily) biaxially oriented. *In re King, supra; W.L. Gore & Associates, Inc. v. Garlock, Inc., supra; In re Oelrich, supra; In re Wilding, supra; Hansgirg v. Kemmer, supra.* Accordingly, the examiner's rejection of claims 13, 14, 16, 17 and 25, under 35 U.S.C. §102 as anticipated by Schjeldahl is reversed. 6

The Rejection of Claims 13 through 17 under 35 U.S.C. §103 Based upon the Combined Disclosures of Schjeldahl and Wyeth.

Wyeth is directed to producing high strength biaxially oriented polyethylene terephthalate beverage containers. The disclosed method involves stretching polyethylene terephthalate having a relatively high inherent viscosity; *e.g.,* at least about 0.85.

It is apparent from the Final Rejection and Answer that the examiner's rejection of the appealed claims under 35 U.S.C. 103 is *not* predicated upon the theory that one having ordinary skill in the art would have been led to employ Wyeth's technique to produce a biaxially oriented balloon for use in

Schjeldahl's catheter. Instead, the examiner presupposes that Schjeldahl discloses a biaxially oriented catheter balloon. The examiner relies upon Wyeth *solely* for the disclosed use of high viscosity polyethylene terephthalate tubing. We refer to page 6 of the Answer, first complete paragraph, wherein the examiner explains the rejection by stating:

Wyeth et al is not being combined with Schjeldahl et al, but merely shows the claimed high viscosity PET (polyethylene terephthalate) and supports the examiners [sic, examiner's] inherency arguments. 7 ... The examiner is not substituting the process of Wyeth et al into Schjeldahl et al since both disclose the same process. 8 Arguments that Wyeth et al can't be scaled down are irrelevant since the examiner is not seeking to scale down that reference to produce the claimed article.

[4] We have already concluded that the examiner factually erred in determining that Schjeldahl expressly or inherently discloses a biaxially oriented catheter balloon. Assuming, *arguendo,* the examiner correctly concluded that one having ordinary skill in the art would have been led to employ a high viscosity polyethylene terephthalate tubing in producing Schjeldahl's catheter balloon, the rejection under 35 U.S.C. §103 must fall because the examiner has not established that the resulting catheter balloon is biaxially oriented. *Uniroyal, Inc. v. Rudkin-Wiley Corp.,* 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988).

Inasmuch as the examiner's rejection under 35 U.S.C. §103 is not predicated upon the theory that one having ordinary skill in the art would have been led to employ a conventional stretch blow molding technique, such as that disclosed by Wyeth, to produce Schjeldahl's catheter balloon, the motivation for such a combination is an issue which was not crystallized on appeal and was not confronted by appellant. However, in view of the examiner's gratuitous statement in the paragraph bridging pages 5 and 6 of the Answer, 9 we are constrained to address that issue.

There appears to be no dispute that one having ordinary skill in the art would have recognized the desirability of producing a biaxially oriented balloon for use in Schjeldahl's catheter, since biaxially oriented materials were known to exhibit high tensile strengths. The thrust of the evidence relied upon by the examiner is that one having ordinary skill in the art would have simply resorted to a conventional stretch molding technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter, specifically, *the technique employed by Wyeth to produce a beverage container.* See paragraph 4 of the Rydell affidavit executed April 25, 1988 and offered in support of the protest in parent application Serial No. 914,108, paragraph 5 of the Pinchuk affidavit (Exhibit III), and paragraphs 4 and 5 of the Kaufman affidavit (Exhibit XII). Interestingly enough, *Wyeth disagrees.* See page 5 of Wyeth's declaration (Exhibit XI). Wyeth points out various differences between the PET bottles produced by his disclosed process and the requirements of a catheter balloon, and then concludes that his process could *not* be used to produce a catheter balloon of the type disclosed by Levy.

We are persuaded by Belcher's affidavits and Wyeth's declaration, notwithstanding the affidavits of Rydell, Pinchuk and Kaufman, 10 that the known processes for producing

biaxially oriented beverage containers, such as that disclosed by Wyeth, could not have been simply scaled down to produce a biaxially oriented catheter balloon for use in medical dilation procedures without the exercise of inventive skill. 11 Based upon the record before us, it would appear unrealistic to conclude that one having ordinary skill in the art would have been led to employ Wyeth's technique, which is designed to produce beverage containers, to produce Schjeldahl's catheter balloon, motivated by a *reasonable expectation* of obtaining a *biaxially oriented* polymeric catheter balloon. *In re O'Farrell,* 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). The rejection under 35 U.S.C. §103 is also reversed.

REVERSED.

Footnotes

Footnote 1. Each of the Schjeldahl references contains essentially the same relevant disclosure. Accordingly, unless otherwise indicated, we have referred to these references collectively as "Schjeldahl," consistent with the approach adopted by both appellant and the examiner.
Footnote 2. See footnote 1.
Footnote 3. Schjeldahl characterizes the catheter balloon as an expander.
Footnote 4. Unless otherwise indicated, all exhibits mentioned are the exhibits to appellant's Brief.
Footnote 5. We recognize that a high burden of proof is required to demonstrate the inoperability of a United States patent. *In re Weber,* 405 F.2d 1403, 160 USPQ 549 (CCPA 1969); *In re Michalek,* 162 F.2d 229, 74 USPQ 107 (CCPA 1947). However, as noted above, Schjeldahl does not disclose a catheter balloon made *of* a biaxially oriented plastic. Therefore, appellant's evidence is not an attack on the operability of Schjeldahl, but quite relevant to the issue of inherency, *i.e.,* whether the catheter balloon disclosed by Schjedahl is inherently biaxially oriented.
Footnote 6. There is evidence of record that Dupont, the assignee of the application, furnished biaxially oriented polyethylene terephthalate to Schjeldahl when he informed Dupont personnel that he required a thin, high strength polymeric film having a tensile strength in the range of 20,000-40,000 psi. See the Schjeldahl affidavit (Exhibit VIII) and the Dengler declaration executed on May 21, 1988 and appended to the protest submitted in parent application Serial No. 914,108. Such facts are not inconsistent with our determination that Schjeldahl does not disclose a biaxially oriented polyethylene terephthalate catheter balloon. The Rydell affidavit appended to the protest in the parent application does not persuade us that Schjeldahl expressly or inherently discloses a biaxially oriented polymeric catheter balloon. See Belcher's affidavit (Exhibit VI).
Footnote 7. Actually, according to the Final Rejection which is incorporated in the Answer, t is the Examiner's position that it would be *prima facie* obvious to use the high viscosity polyethylene terephthalate of Wyeth in Schjeldahl et al to produce the claimed product (page 4, the only complete paragraph).
Footnote 8. It is apparent from our reversal of the examiner's rejection under 35 U.S.C. §102 that, in our opinion, Schjeldahl discloses neither a biaxially oriented catheter balloon nor a molding process which involves stretching.
Footnote 9. The noted statement provides:
Certainly in the least there was an *invitation* to make a biaxially oriented catheter balloon at the time of the Schjeldahl et al invention. Additionally injection stretch blow molding to produce biaxially oriented articles was well known at the time of the Schjeldahl et al invention (emphasis supplied).
Footnote 10. We agree with appellant that the credentials of Belcher and Wyeth in the relevant art appear more impressive than those of protestor's experts. According to the affidavit appearing as Appendix V, Belcher authored the chapter called "Blow Molding of Polymers" for the fifth edition of the Plastic Engineering Handbook of the Society of Plastics Industry. In addition, Belcher authored two chapters, one on "injection blow molding" and one on "stretch blow molding" for the Blow Molding Handbook of the Society of Plastics and Engineers. We consider Wyeth's opinion with respect to the capabilities of his own invention entitled to greater weight than the opinions of Rydell, Pinchuk and Kaufman.
Footnote 11. We find it somewhat unrealistic in light of the apparent disparities in size and function, Belcher's affidavits and Wyeth's declaration, that Pinchuk and Kaufman equate beverage bottles to catheter balloons. See paragraph 10 of the Pinchuk affidavit (Exhibit III), wherein it is stated s a blow molded polymeric article, a bottle and a catheter balloon are equivalent.
See, also, paragraph 4 of the Kaufman affidavit (Exhibit XII), wherein it is stated that anyone with ordinary skill in the plastics art would know how to make a biaxially oriented PET balloon; it would be similar to making a biaxially oriented PET bottle because both catheter balloons and bottles are equivalent structures - they are both fluid containers.

- End of Case -

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